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STATUTORY STORAGE PERIOD FOR EMBRYOS

**REPORT BY THE HUMAN
FERTILISATION AND EMBRYOLOGY
AUTHORITY TO THE
HEALTH MINISTERS OF THE
UNITED KINGDOM**

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The Rt Hon Stephen Dorrell MP
Secretary of State for Health
Richmond House
79 Whitehall
SW1A 2NS

19 July 1995

Dear Secretary of State

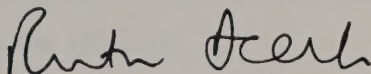
The Statutory Storage Period for Embryos

Earlier this year the Authority was asked to advise the government on the issues surrounding the statutory storage period for human embryos, and to make recommendations about whether the period should be extended.

I now enclose the Authority's report, which has been prepared taking account of a wide range of views and interests. The Authority recommends that the statutory period should be extended by regulations. This will allow people who have stored embryos more time to decide whether or how they should be used.

I hope the report will be helpful to the government and Parliament in coming to a decision on how to proceed on this issue.

Yours faithfully



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REPORT OF THE HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY ON THE STATUTORY STORAGE PERIOD FOR EMBRYOS

Introduction

1. Parliament laid down in the Human Fertilisation and Embryology Act 1990 (HFE Act) that the maximum storage period for embryos is 5 years. The Act became effective on 1 August 1991 and for embryos already in storage on that date, the 5 year period will end on 31 July 1996. Any such embryos which have not been used by that date, for the purposes for which consent has been given, will have to be allowed to perish.

2. Parliament, however, can alter the maximum storage period for embryos using a regulation-making power contained in the HFE Act. The Human Fertilisation and Embryology Authority (HFEA) has been asked by the Secretary of State for Health to advise on the issues surrounding the statutory storage period for embryos. This report considers the social, ethical, scientific, legal and practical issues arising from the current maximum storage period. It recommends that the maximum period should be increased (para 46).

Background

3. An embryo is produced *in vitro* when a sperm enters an egg and fertilises it outside the body. The fertilised egg then begins to divide and develop to become an embryo. In IVF (In Vitro Fertilisation) treatment, embryos are transferred to a woman or may be stored frozen for future use. Embryos may also be produced and used in research under the strict controls set out in the HFE Act.

4. At the time of transfer, embryos normally consist of only two or four cells and are barely visible to the human eye. Although embryos transferred into a receptive womb have the potential to become human beings, there is no guarantee that they will develop into a pregnancy. Many embryos fail to implant, just as in natural conception.

The HFE Act

5. In 1990, Parliament passed the HFE Act to establish controls over:

- research involving the creation or use of human embryos;
- infertility treatments involving IVF or the use of donated eggs or sperm; and

- the storage of eggs or sperm or embryos.

The Role of the HFEA

6. Since 1 August 1991, clinics wishing to carry out any of these activities have been obliged first to obtain a licence from the HFEA, the regulatory body set up under the HFE Act. The HFE Act also requires the HFEA to:

"keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this [HFE] Act, and advise the Secretary of State, if he asks it to do so, about those matters".

The Issue Under Review

7. Section 14(4) of the HFE Act sets the maximum storage period for embryos at 5 years. A regulation-making power in the Act (at section 14(5)b) could allow this maximum period to be changed in circumstances to be specified. Whether regulations should be made and in what circumstances change may be permitted are matters for the Secretary of State for Health and, ultimately, for Parliament to decide.

8. Clinics have informed the HFEA that in June 1995 there were about 52,000 embryos in storage and that for about 9,000 of these, the 5 year storage period ends on 31 July 1996. As the legislation currently stands, if these embryos have not by then been used for any purpose for which consent has been given, they must be allowed to perish.

9. As 31 July 1996 approaches, there is growing concern in licensed clinics and among patients at the prospect of leaving large numbers of embryos to perish which might be used in treatment. The media have also taken an interest in the matter.

10. At the request of the Secretary of State, the HFEA has considered whether there is a case for changing the 5 year limit. In drawing up its report, the Authority has taken account of a wide range of views and interests, including information it obtained from surveys of licensed treatment clinics and patients.

Why People Wish to Store Embryos

11. IVF involves the retrieval of eggs from a woman's ovaries under sedation or general anaesthetic. The woman is usually given drugs which cause several eggs to mature in one monthly cycle rather than the normal single egg. The eggs are then collected and fertilised by sperm to produce embryos for use in treatment. The procedures are not without physical risk and

discomfort for the woman and emotional stress for the couple.

12. While many embryos (on average 6) may be produced during a single IVF treatment cycle, the HFEA Code of Practice allows clinics to transfer only a maximum of 3 to a woman's womb in any one monthly cycle. This is to reduce the likelihood of multiple pregnancy (triplets or more) which could pose a threat to the health and welfare of the mother and her babies.

13. If more than 3 embryos have been produced, spare embryos can be stored frozen for use in a later treatment cycle. Embryos may also be frozen where the woman's health would be at risk if any embryos were replaced immediately (eg in cases of ovarian hyperstimulation syndrome). Using frozen-thawed embryos in another treatment cycle prevents the need for repeated drug stimulation and egg retrieval. (It is not currently possible to store unfertilised eggs for future treatment.)

14. Storage also gives couples time to decide what should happen to embryos not required for their own treatment. Such embryos may be donated to another couple or for research, or may be allowed to perish. If a couple decides to donate embryos, storage also ensures that there is sufficient time for the donating couple to be appropriately counselled and screened. Permission may be varied to allow donation or research at any time.

Consent

15. Under the HFE Act, people must give prior written consent to the storage and use of their embryos, whether:

- a. for their own treatment,
- b. for the treatment of others, or
- c. for research.

16. Before giving consent, the man and woman whose sperm and eggs (collectively known as gametes) are to be used to produce embryos must be given a suitable opportunity to receive appropriate counselling and be provided with relevant information. They must complete separate consent forms and their consents must be compatible as future use of embryos is dependent on the consent of both parties.

17. The consent forms state that the maximum statutory storage period is 5 years. The couple can say whether they consent to the storage of the embryos for a shorter period. The consent form also requires each to say what is to happen to the embryos if they die or become mentally

incapacitated. Either party may change their consent at any time before the embryos are used (as noted above in para 14).

Counselling and Information

18. The HFEA sent a questionnaire to licensed clinics to ask what issues relating to embryo freezing and storage they covered in counselling. Most clinics said they discussed with their patients the implications of the statutory storage period, as well as the survival rate of embryos after thawing and the likely pregnancy rate from a frozen-thawed embryo transfer. Fewer than 1 in 5 patients consenting to the storage of embryos sought additional counselling about the matter.

19. From a survey of patients, it was clear that most felt they received adequate information from their respective clinics about embryo storage.

The Current Maximum Storage Period

20. The Warnock Committee, reporting in 1984, recommended that embryos should not be stored for longer than 10 years. This was because of the legal and ethical complications which might arise where the couple whose gametes had been used died, separated or divorced, and because there was little knowledge about the possible effects of long term storage.

21. There was little debate in Parliament about the appropriate length of time for storing embryos. No medical or scientific reasons why embryos should not be stored for long periods were identified, and the five year limit was apparently chosen for reasons of caution. However, Parliament recognised the need for flexibility by the provision in the HFE Act of a regulation-making power to alter the storage period. The complications identified by the Warnock Committee, arising from the couple dying, separating or divorcing, were resolved by the consent provisions of the HFE Act.

22. The first pregnancy from a frozen-thawed embryo transfer was reported in Australia in 1983 and the first live birth took place in the same year in the Netherlands. Since then, several thousand children have been born following frozen-thawed embryo transfers and the technique is now established clinical practice.

23. In 1993, the HFEA set up a Working Group on Embryo Freezing to review developments in freezing techniques and their potential impact on regulated treatment, storage and research.

24. The Working Group reported to the Authority in February 1994. It found no evidence of

lack of safety for patients or their potential children in the use of frozen embryos in treatment. Although the implantation rate is lower with frozen-thawed embryo transfers than with fresh embryo transfers, miscarriage rates are no different and one major study found that the incidence of congenital abnormalities was lower than that observed with fresh embryos. The Working Group was assured by experts that there is no reason to believe that viable embryos¹ stored in proper conditions would suffer harm from longer, even indefinite, storage. Animal studies to date suggest no long-term genetic implications from current freezing methods.

25. Recent research following up the development of children born from frozen embryos is reassuring. The conclusions of a French study of behavioural changes in mice born from frozen embryos have been withdrawn by the authors. Notwithstanding, the HFEA is keen to see further long-term follow-up studies of children born from what are still relatively new techniques.

Review of the Current Maximum Storage Period

Ethical and Social Considerations

26. Principles: The main ethical principles which apply to embryo storage were clearly established by Parliament in the HFE Act. They are as follows:

- embryos may be produced and used for treatment or for research and they may be stored;
- there should be a maximum period for the storage of embryos;
- the specific consent of men and women providing sperm and eggs must be obtained before their gametes or embryos produced from them can be used or stored for any purpose;
- whilst consent may be varied, embryos may only be used for the purposes specified; and
- embryos may be allowed to perish.

27. In addition, the HFE Act conferred on the HFEA the responsibility for deciding what is necessary or desirable for the purpose of providing treatment services or necessary for the purposes

¹ There is agreement among scientists that the quality of the embryo is the determining factor in its viability.

of research. Therefore, as with all its thinking, the HFEA has also been guided by:

- the respect which is due to human life at all stages in its development;
- the right of people who are or may be infertile to proper consideration of their request for treatment;
- a concern for the welfare of children; and
- a recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.

28. Interests: The interests which need to be taken into account in considering the maximum storage period for embryos are complex and involve patients, clinics, and children who may be born as well as society more generally.

29. Couples who have to rely on infertility treatment to help them conceive are limited in the freedom they have over their reproduction. They have fewer choices as to timing than those who can conceive naturally and they need to rely on a third party for clinical judgment and expertise. In addition, the cost of treatment often limits the number of attempts a couple can make to have a baby.

30. The clinics' interests are in being able to meet their obligations by keeping the embryos stored safely and staying in touch with the couples concerned, often over long periods of time. On the whole, clinics meet these obligations responsibly and must be allowed to continue to do so.

31. Society in general needs to be confident that the special status of the embryo continues to be recognised whilst embryos are stored. It needs to be satisfied that the welfare of children who may be born is properly considered before treatment services are provided. It also needs to be reassured that clinical practice will not run ahead of the ethical and social considerations involved if embryos are stored for long periods.

The HFEA's views

32. The HFEA considers that an upper limit on the storage period is essential lest some embryos be stored indefinitely. The Authority has heard no arguments to persuade it that indefinite

storage is necessary or desirable for the purposes of a couple's own treatment or the treatment of others or necessary for research.

33. On the other hand, the HFEA is aware that some people find it very difficult to decide what is to happen to embryos which they do not wish to use for their own treatment, and put off the decision as long as possible. However, having accepted the principle of specific consent, the Authority believes that such decisions must not be avoided indefinitely. Otherwise, embryos could forever be in storage, neither used nor allowed to perish.

34. There are also practical considerations which make indefinite storage of embryos undesirable. For example, it would become impossible to keep track of those who provided the gametes and there would be increasing problems in meeting the physical demand for secure storage space.

35. The Authority has found no particular medical, scientific, moral or social basis for limiting the storage period for embryos to 5 years.

36. The main arguments for extending the storage period, which were supported by the responses to the HFEA questionnaires, are as follows:

- couples would have greater flexibility and control over planning their families;
- the additional risk and stress of further egg retrieval, if spare embryos were destroyed, would be avoided;
- couples would have more time to decide whether to continue treatment and what to do with the embryos;
- couples would have more time to prepare for further treatment, taking account of their economic and family circumstances;
- young women with serious illness would benefit, especially cancer patients who store embryos in case their treatment leaves them infertile, in that it would reduce the time pressure on them to use the embryos. Five years is unlikely to be long enough for them to complete their families.

37. The HFEA also recognises that there are concerns about increasing the storage period.

These have been identified as the following:

- "twins" produced *in vitro* at the same time could be born more than 5 years apart;
- embryos stored in one generation could be used in subsequent generations;
- women could store embryos in order to delay motherhood, leading to more older women seeking treatment;
- difficulties may arise for clinics in keeping in touch with patients who have embryos in storage for extended periods;
- practical difficulties may arise for clinics in the accumulation of large numbers of embryos;
- couples who do not want to use their embryos for their own treatment might find it difficult to decide what to do with them and simply put off making a decision, causing an increased period of anxiety for themselves;
- the cost of storage may be an additional burden for patients.

38. The HFEA has concluded that the benefits of extending the maximum storage period significantly outweigh the possible problems, although the Authority has taken these concerns into account in preparing proposals for extending the storage period.

39. The HFEA's proposals are built on its current requirements for good practice. In considering treatment using embryos which have been stored for any period of time, clinics are obliged to take account of the welfare of the child who may be born and of any existing children. This includes consideration of the effects on children of being born from embryos produced *in vitro* together, but at a different time from others produced at the same time or even in another generation. It also requires the age and health of the prospective parents to be taken into account when the decision is made to offer treatment. In addition, people considering embryo storage for any period, whether for medical or social reasons, should be fully informed about the implications of doing so, including the cost, and they should have continuing access to counselling. Regarding the practical difficulties, clinics should be fully aware of their responsibilities and can be monitored to ensure that they discharge them appropriately.

40. If the maximum storage period is extended, the HFEA will also consider whether it should make any changes to the guidelines for good practice in its Code of Practice.

Legal considerations

41. The HFEA is aware that under the terms of 14(5)b of the HFE Act, regulations will have to identify specific circumstances in which an extension beyond 5 years is permissible.

42. As the arguments for extending the storage period are mainly medical and social these could be the specified circumstances. It would be proper to expect the patient to reach conclusions about extending the storage period in consultation with the clinician involved. It would also be appropriate to require that counselling should be available and a specific renewed consent obtained.

Options for Change

43. Having concluded that the current maximum storage period should be extended, the HFEA offers the following principles in seeking to establish a new maximum:

- the welfare of any child who may be born and of any other child who may be affected should be taken into account;
- a maximum storage period need not be the only option for either patients or clinics; a shorter period may be appropriate and can be specified by the Authority on a clinic's licence or by the couple on the consent forms;
- the storage period should be extended only with the specific consent of the couple;
- consent for the use of the embryos may be varied during the extended storage;
- people should have as much control as possible over their own reproductive lives;
- the Authority does not wish to see an increase in the age of women being treated by the clinics it regulates, although it recognises that each case should be considered on its merits and therefore there might be exceptions;
- for reasons of equal treatment of men and women affected by illness, the maximum period for which embryos should be stored should be in line with that for men who store

sperm for their own use (regulations allow people in exceptional medical circumstances to store their eggs and sperm until they are 55, but currently it is only possible to freeze sperm).

The HFEA's Conclusions

44. The HFEA considered that there was an argument for amending the HFE Act so as to rely on the principles of the welfare of the child and the informed consent of those providing the gametes from which embryos are produced. This would allow each case to be considered on its merits and the maximum storage to be set according to circumstances, taking into account what is necessary or desirable. However, the Authority recognises that this would be a significant change from the current arrangements and one which would require further consideration and public debate.

45. Bearing in mind the constraints of current legislation, the Authority has concluded that regulations to extend embryo storage to 10 years, for medical or social reasons compatible with the welfare of the child, would provide a practical way forward. Ten years would allow couples more control over their lives without creating unmanageable numbers of embryos in storage. An option to allow extension beyond 10 years in exceptional cases would place women who may wish to store embryos in the same position as men who can store gametes until they are 55 for exceptional medical reasons. These extensions should be combined with review procedures which would serve as an important, regular reminder to clinics and couples storing embryos of the special status of embryos, and of the need to address the issue of what to do with them. In the Authority's view this would be a properly cautious approach.

46. The HFEA therefore proposes the following:

- the normal storage period for embryos should remain at 5 years;
- for medical or social reasons there should be an option at the end of 5 years to extend the storage period up to 10 years with consent specifically renewed by the couple. Both the reasons for which extended storage was agreed and the consent should be reviewed in the 7th and 9th year by the clinic and the couple together;
- there should be a presumption against storage beyond a 10 year period;
- this presumption may be rebutted and the period extended in the case of special categories of patients (such as cancer patients and other cases where the woman has ceased

or might cease to produce her own eggs);

- any extension beyond 10 years would require renewed consent and a review of the case by the clinic with the couple concerned every two years;
- the HFEA should specifically monitor the activities of clinics in respect of embryo storage beyond the 10 year period; and
- in any event, whatever the storage period, storage should not continue after the woman reaches the age of 55.

47. The Authority considered other approaches to extending the embryo storage period as follows:

a. a natural time limit, such as a woman's childbearing years: Although this limiting factor was initially attractive, the HFEA concluded that it was virtually impossible to define adequately. The average age for the menopause is about 51 years. However, some women continue to ovulate well into their 50s, whilst others undergo premature menopause as early as their teens.

b. a fixed time limit: The HFEA considered that a fixed limit of 10 or, possibly, 15 years would meet the storage needs of most couples, without placing an undue burden on clinics. The burden could be minimal if clinics played an active role from the outset in helping couples make the right decisions for them. However, even a maximum storage period of 15 years might not be adequate in a few very exceptional cases, such as young cancer patients. There might be other "hard" cases which have not yet been recognised.

Guidance for Clinics

48. The HFEA recognises that, to support the approach outlined in paragraph 46, guidance on good practice for licensed centres would be helpful to prevent problems developing in the future. This could be incorporated in the Code of Practice in due course. Good practice would include:

- for embryos currently in storage, each couple to be contacted individually by the clinic and their specific consent to further storage obtained;
- the storage period to be agreed between the clinic and the couple concerned and included

in the couple's consent forms;

- clinics to offer to take an active part in helping couples reach the right decision for them about what is to happen to embryos;
- couples to acknowledge in the consent forms that they have a responsibility to inform the clinic of any change in their circumstances which might affect the storage of embryos; and
- couples who store embryos for their own use to acknowledge in their consent forms that the embryos will be allowed to perish on a particular date unless they use them beforehand or change their consent to allow an alternative use. (If embryos were produced using donated gametes, the consents of both parties must be checked to ensure that they remain compatible.)

49. The HFEA will expect clinics to satisfy themselves that they have done everything possible to contact couples with whom they have lost touch. This should include writing to the last known address, telephoning and contacting the couple's general practitioner or any other suitable third party. Clinics will, of course, need to take account of the confidentiality provisions of the HFE Act and take care not to divulge information about the couple's treatment, as well as any specific requirement by the patients about contacting them.

50. The HFEA recognises that, whilst clinics should do all they can to stay in contact with patients who have embryos in storage, there is a limit to what they can reasonably achieve. Indeed the responsibility of the couple to stay in contact with the clinic where they have embryos in storage should always be stressed.

51. Whatever the conclusion reached by the Secretary of State and Parliament, guidance will also be needed in the short term to advise clinics what they should tell patients who have had embryos in storage for over 4 years. Standard information to be given to patients or donors should include:

- a reminder of the date on which their embryos were stored;
- the current legal position in respect of the maximum storage period for embryos;
- that the matter is under review and that it is for the Department of Health and

Parliament to change or affirm it;

- that they may wish to make decisions about the use of their embryos for implementation before the expiry of the 5 year period; and
- that the clinic will provide any information or counselling needed by patients to help them in the decision-making process.

52. The HFEA will seek to publicise that the statutory storage period for embryos is 5 years and that it is coming to a close for all embryos in storage when the HFE Act became effective on 1 August 1991.

Conclusions

53. The HFEA has concluded that it is desirable to extend the storage period for embryos beyond the current maximum of 5 years. It recommends the formula set out in paragraph 46 of this report as a way of doing so to meet all foreseeable needs without the risk of harm to any other interest. In the meantime, guidance will be given to clinics to enable them to help patients in the coming year.

Human Fertilisation &
Embryology Authority
July 1995



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19 December 1995

Dear Colleague

**REPORT BY THE HUMAN FERTILISATION AND EMBRYOLOGY
AUTHORITY ON THE STATUTORY STORAGE PERIOD FOR
EMBRYOS**

I enclose a copy of the above report which has been published today.

Regulations will be published early in 1996 to allow the five-year limit, currently imposed under Section 14(4) of the Human Fertilisation and Embryology Act, to be extended.

Yours faithfully

John Sharpe
Health Promotion Division

Further copies can be obtained from:

The Department of Health, Room 417 Wellington House, 133-155 Waterloo Road, London SE1 8UG.
Tel: 0171-972-4192.